DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

95173d

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

NOV 17 2004

WARNING LETTER

VIA FEDERAL EXPRESS

Horst Pajunk
President
Pajunk GmbH
Karl-Hall-Strasse 1
D-78187 Geisingen
Federal Republic of Germany

Dear Horst Pajunk:

During an inspection of your firm located in Geisingen, Germany on June 14, 2004, through June 17, 2004, our investigator from the United States Food and Drug Administration (FDA) determined that your firm manufactures a number of products including, but not limited to, Sprotte Cannula, EpiLong and Epispin Systems for Epidural Anesthesia, Plexus Anesthesia and Peripheral Nerve Blocks, Trocar Systems, Balloon Systems, Modular Laparoscopic Handle Instruments, TrokaBone/Trokabone Sternal Bone Marrow Aspiration/Biopsy Puncture Cannula, DeltaCut Biopsy System, Organ Puncture/Biopsy Cannula, and VarioSafe syringes, applicators, and cannula. These products are devices under a United States law, the Federal Food, Drug, and Cosmetic Act (section 201(h) of the Act, (21 U.S.C. § 321(h)).

This inspection revealed that these devices are adulterated within the meaning of section 501(h) of the Act (21 U.S.C. § 351(h)), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation found at Title 21, Code of Federal Regulations (CFR), Part 820. Significant violations include, but are not limited to, the following:

1. Failure to establish and maintain procedures to evaluate complaint files to determine whether a complaint represents a Medical Device Report (MDR) reportable event, as required by 21 CFR 820.198(a)(3).

   For example, during our inspection, your firm stated that there are no established internal procedures for the review and evaluation of complaints for MDR reportable events.

2. Failure to maintain MDRs in a separate portion of the complaint files or otherwise clearly identified manner as required by 21 CFR 820.198(d).

   For example, complaint number [redacted] was reported to FDA as an MDR. The complaint file did not clearly identify that it represented an MDR

reportable event and was not maintained in a separate portion of the complaint files.

3. Failure to adequately establish and maintain process control procedures necessary to ensure conformance to specifications, as required by 21 CFR 820.70(a)(1).

   For example, firm management stated that the Process Control Procedures require employees to initial records after scanning with the [redacted] scanner. The [redacted] scanner is used to record process control steps, i.e., sterilization process step "AH: ETO-Sterilisation Ausser-Haus-Lieferant: IBA." An employee stated that the [redacted] scanner was not working on the days that she signed the Laufkarte (Running Cards) [redacted] and [redacted] to verify "Off site delivery to Sterilisation provider" in accordance with the Process Control Procedures.

4. Failure to establish procedures for the identification, documentation, validation or, where appropriate, verification, review, and approval of design changes before their implementation, as required by 21 CFR 820.30(i).

   For example, the firm's design change procedure (Quality Manual, Safety Issues and Control of Design Changes, Sections 6.11, 6.12, 6.14) does not require that design changes be reviewed and approved before implementation.

5. Failure to adequately establish and maintain document control procedures, as required by 21 CFR 820.40. For example:

   a. Your firm does not have adequately established document control procedures that define the signature and date requirements for documentation of required records. Specifically, the Investigator observed that employee training records used quotation marks to document the trainer and date; the device history record (DHR), Laufkarte (Running Cards) [redacted] and [redacted], used quotation marks and other symbols to document dates; and the Employee Introduction Checklist ([redacted]) was signed by approving individuals with no signature date.

   b. Your firm has no established procedures for the review and approval of procedures prior to issuance.

   c. Your firm has no procedures requiring that document approvals be documented by the approving individual with an approval date.

d. Your firm has no procedures for the distribution and use of current documents. Specifically, there is no procedure for the handling of Administration Form Revisions [redacted]. This form addresses document changes but there are no procedures for use of this form. There are no procedures requiring that document approvals be documented by the approving individual. Also, it was observed that an obsolete document, document development plan revision [redacted], was used when the current version was [redacted]

The above stated inspection also revealed that your devices are misbranded under section 502(t)(2) of the Act (21 U.S.C. 352(t)(2)), in that your firm failed to furnish material or information as required under section 519 of the Act and regulations implementing that section at Title 21 Code of Federal Regulations (21 CFR), Part 803 – Medical Device Reporting (MDR). Significant violations include, but are not limited to, the following:

1. Failure to develop, maintain, and implement written MDR procedures, as required by 21 CFR 803.17.

   For example, your firm stated during the inspection that it does not have an internal formal system for evaluating adverse events and submitting the required MDR reports to FDA.

2. Failure to report to FDA within 30 days whenever the manufacturer receives or otherwise becomes aware of information, from any source, that reasonably suggests that a device marketed by the manufacturer may have caused or contributed to a death or serious injury, as required by 21 CFR 803.50(a). For example:

   a. A patient injury associated with the use of the Pajunk Sprotte Needle was placed under Complaint number [redacted] on 04/15/03, but an MDR [redacted] was not submitted to FDA until 06/16/03.

   b. On 09/03/02, your firm documented a complaint (Complaint number [redacted]) with an injury involving a Pajunk Sprotte Needle with Article [redacted]. The event was not reported to FDA through an MDR within thirty days after becoming aware of the incident and no documented reason for not reporting was noted.

3. Failure to provide known or reasonably known information that corresponds to the format of FDA Form 3500A (MEDWATCH, for use by user-facilities, distributors and manufacturers for MANDATORY reporting), as required by 21 CFR 803.52. For example:

a. Your firm did not complete the patient information in Section A of FDA Form 3500A for MDR [redacted] that was submitted to FDA. An explanation of why such information was not provided and the steps taken to obtain such information was not provided.

b. Your firm did not complete the evaluation codes and additional manufacturer narrative in Sections G and H of FDA Form 3500A for [redacted] An explanation of why such information was not provided and the steps taken to obtain such information was not provided.

This letter is not intended to be an all-inclusive list of violations at your facility. It is your responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the Inspectional Observations, Form FDA 483 (FDA 483), issued at the closeout of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality assurance systems. You should investigate and determine the causes of the violations, and take prompt actions to correct the violations and to bring your products into compliance.

If you fail to take prompt corrective action, FDA may take regulatory action without further notice to you. Given the serious nature of these violations of the Act, FDA may detain your products without physical examination upon entry into the United States under section 801(a) of the Act (21 USC 381(a)), until the violations described in this letter are corrected, because the products appear to be adulterated within the meaning of section 501(h) of the Act (21 USC 351(h)).1 In addition, United States federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of government contracts.

In order to remove your products from detention, you should provide a written response to this Warning Letter as described below and correct the violations described in this letter. We will notify you if your response is adequate, and we may need to re-inspect your facility to verify that the appropriate corrections have been made.

We received a response from [redacted] Consultant, dated August 25, 2004, concerning our investigator's observations noted on the FDA 483. We have reviewed your response and have concluded that it is inadequate for the following reasons:

1. Your firm stated that procedures would be developed for the review and evaluation of complaints for MDR reportable events, process control, design changes, document control, and MDRs. These procedures were not submitted in your response for our review. Please submit these procedures for FDA's review.

2. Your firm stated that employee re-training would be conducted in process control, document control, and MDR procedures. These procedures and the training records were not submitted in your response for our review. Please submit these procedures and training records for FDA's review.

We have also concluded that other portions of your response are inadequate for the following reasons:

Your response dated August 25, 2004, provided updated MEDWATCH report information for [redacted] for sections A, G, and H. You must submit a supplemental MEDWATCH report with this information to FDA, as required by 21 CFR 803.56.

Please notify this office in writing within fifteen (15) working days from the date you receive this letter, of the specific steps you have taken to correct the noted violations, including an explanation of how you plan to prevent these violations, or similar violations, from occurring again. Include all documentation of the corrective action you have taken. If you plan to make any corrections in the future, include those plans with your response to this letter as well. If the documentation is not in English, please provide a translation to facilitate our review.

Your response should be sent to the Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Enforcement B, Orthopedics, Physical Medicine, and Anesthesiology Devices Branch (OPMAD), 2094 Gaither Road, Rockville, Maryland 20850 USA, to the attention of Bill MacFarland, Chief OPMAD.

If you need help in understanding the contents of this letter, please contact Bill MacFarland at the above address or at (240) 276-0120 or FAX (240) 276-0129.

Sincerely yours,

Timothy A. Ulatowski
Director
Office of Compliance
Center for Devices and
Radiological Health